

INSURANCE DIVISION[191]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 510B.3, the Insurance Division hereby gives Notice of Intended Action to amend Chapter 59, “Pharmacy Benefits Managers,” Iowa Administrative Code.

Iowa Code chapter 510B provides for the Iowa Insurance Commissioner’s administration of the provisions of Iowa Code chapter 510B relating to the regulation of pharmacy benefits managers. The proposed amendments to Chapter 59 are intended to do the following:

1. Implement 2015 Iowa Acts, House File 395.
2. Incorporate the findings in *Pharm. Care Mgmt Ass’n v. Gerhart*, No. 4:14-CV-00345 (S.D. Iowa Feb. 18 and Sep. 8, 2015, appealed to the U.S. Court of Appeals for the Eighth Circuit, *PCMA v. Gerhart and Miller*, No. 15-3292).
3. Clarify duties of pharmacy benefits managers that will allow the Commissioner to administer Iowa Code chapter 510B. Pharmacy benefits managers are engaged to stand in the stead of insurers and other entities to administer and manage prescription drug benefits provided under the health insurance plans issued by the insurers and other entities. The Insurance Division has the duties to regulate and supervise the conducting of the business of insurance in Iowa, pursuant to Iowa Code section 505.1. The Insurance Commissioner has general control, supervision, and direction over all insurance business transacted in the state, pursuant to Iowa Code section 505.8, and must provide assistance to the public and to consumers of insurance products in Iowa. The services provided by pharmacy benefits managers affect both the public (which includes pharmacies) and consumers of insurance products. Further, the services provided by pharmacy benefits managers not only contribute to the efficiency of how insurers administer the payment of benefits, but also contribute to insurance costs reflected in the rates charged by insurers to consumers of insurance. The Commissioner is required to review risks, costs and rates. (See, e.g., Iowa Code chapter 513C and sections 505.8(1), 505.8(19) and 514A.13.) The amendments provide means by which the Insurance Division and the Commissioner can obtain the information necessary to determine whether insurers, through their pharmacy benefits managers, are providing uniform, fair, administratively efficient and cost-efficient services to insurers, pharmacies and consumers.

The Division intends that this rule making will become effective June 1, 2016.

Any interested person may make written suggestions or comments on the proposed amendments on or before March 22, 2016. Such written materials should be directed to Rosanne Mead, Iowa Securities and Regulated Industries Bureau, Iowa Insurance Division, Two Ruan Center, Fourth Floor, 601 Locust Street, Des Moines, Iowa 50319; fax (515)281-3059; e-mail rosanne.mead@iid.iowa.gov.

Also, there will be a public hearing on March 22, 2016, at 10 a.m. at the offices of the Iowa Insurance Division, Two Ruan Center, Fourth Floor, 601 Locust Street, Des Moines, Iowa, at which time persons may present their views either orally or in writing. At the hearing, persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the amendments.

Any persons who intend to attend the public hearing and have special requirements, such as those relating to hearing or mobility impairments, should contact the Division and advise of specific needs.

The Insurance Division’s general waiver provisions of 191—Chapter 4 apply to this rule.

These amendments will impose no fiscal impact to the State.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code chapter 510B.

The following amendments are proposed.

ITEM 1. Rescind the definitions of “Clean claim,” “Corrective action plan” and “Pharmacist” in rule **191—59.2(510B)**.

ITEM 2. Amend rule **191—59.2(510B)**, definitions of “Complaint” and “Pharmacy,” as follows:

“Complaint” means a written communication expressing a grievance or an inquiry concerning a transaction between a pharmacy benefits manager and from a pharmacy to a pharmacy benefits manager that makes an inquiry, requests information, or expresses a grievance and includes, but is not limited to, the following:

1. A comment on, contest or appeal by a pharmacy, as permitted by Iowa Code section 510B.8(3) and rule 191—59.5(510B), of a pharmacy benefits manager’s maximum reimbursement amount rate or maximum reimbursement amount list.

2. Any pharmacy’s appeal or request for an independent third-party review of an audit report pursuant to subrule 59.4(6).

3. Any request by a pharmacy for an independent third-party review of a termination or suspension decision pursuant to paragraph 59.6(3) “e.”

4. Any inquiries from the commissioner pursuant to subrule 59.8(3).

“Pharmacy,” except as used in paragraph 59.4(1) “b,” means “pharmacy” as defined in Iowa Code section 155A.3 and includes “pharmacist,” as defined in Iowa Code section 155A.3, and a pharmacy services administrative organization while acting in its role as a representative of a pharmacist or pharmacy. For purposes of this definition, “pharmacy services administrative organization” means an entity that, while acting in its role as a representative of a pharmacy, provides contracting services on behalf of pharmacies with payers and with pharmacy benefits managers, consolidated reimbursement services for pharmacies, and other business support for pharmacies.

ITEM 3. Adopt the following **new** definition in rule **191—59.2(510B)**:

“Maximum reimbursement amount,” as defined in Iowa Code section 510B.1(6), includes but is not limited to a pricing rate for generic and therapeutically, pharmaceutically equivalent drugs such as maximum allowable cost, federal upper limit pricing, generic effective rate pricing, or other pharmacy benefits managers’ pricing strategies.

ITEM 4. Adopt the following **new** subrule 59.3(4):

59.3(4) For purposes of this rule, “clean claim” means a claim which is received by any pharmacy benefits manager for adjudication and which requires no further information, adjustment or alteration by the pharmacy or the covered individual in order to be processed and paid by the pharmacy benefits manager. A claim is a clean claim if it has no defect or impropriety, including any lack of substantiating documentation, or no particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this chapter. A clean claim includes a resubmitted claim with previously identified deficiencies corrected.

ITEM 5. Amend paragraph **59.4(1)“b”** as follows:

b. Any audit which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist as defined in Iowa Code section 155A.3;

ITEM 6. Amend subparagraphs **59.4(1)“j”(4)** and **(6)** as follows:

(4) Any clerical or record-keeping error of the pharmacy, including but not limited to a typographical error, scrivener’s error, or computer error, regarding a required document or record shall not be considered fraud by the pharmacy under paragraph 59.5(3) 59.6(3) “a” or under a pharmacy’s contract with the pharmacy benefits manager.

(6) If a pharmacy has entered into a corrective action plan with a pharmacy benefits manager, ~~errors that are a result of the pharmacy’s failure to comply with such plan may be subject to recovery.~~ and if the pharmacy fails to comply with the corrective action plan in a manner that results in overpayments being made by the pharmacy benefits manager to the pharmacy, the pharmacy benefits manager may recover the overpaid amounts. For purposes of this paragraph, “corrective action plan” means an agreement entered into by a pharmacy benefits manager and a pharmacy which is intended to promote accurate submission and payment of pharmacy claims.

ITEM 7. Amend subrule 59.4(6) as follows:

59.4(6) Any pharmacy's appeal or request for an independent third-party review of an audit report shall be considered a complaint and shall be included in the report required by subrule ~~59.7(2)~~ 59.8(2).

ITEM 8. Renumber rules **191—59.5(510B)** to **191—59.10(505,507,507B,510,510B,514L)** as **191—59.6(510B)** to **191—59.11(505,507,507B,510,510B,514L)**.

ITEM 9. Adopt the following new rule 191—59.5(510B):

191—59.5(510B) Disclosure of national compendia used.

59.5(1) Pursuant to Iowa Code section 510B.8(3), in each contract between a pharmacy benefits manager and a pharmacy beginning or renewed on or after July 1, 2016, a pharmacy benefits manager shall identify how and where pharmacies may find the names of the national compendia or other services the pharmacy benefits manager has used to obtain the pricing data incorporated in the calculation of the maximum reimbursement amount for the formulary drugs included in the list made available to pharmacies pursuant to rule 191—59.7(510B).

59.5(2) Pursuant to Iowa Code section 510B.8(3), a pharmacy benefits manager shall provide a process to allow a pharmacy to comment on, contest or appeal a maximum reimbursement amount rate or maximum reimbursement amount list.

59.5(3) Any pharmacy's comment on, contest or appeal of a maximum reimbursement amount rate or maximum reimbursement amount list shall be considered a complaint and shall be included in the report required by subrule 59.8(2).

ITEM 10. Amend renumbered paragraphs **59.6(3)“b”** and **“e”** as follows:

b. ~~A pharmacy shall not be terminated or suspended from the pharmacy benefits manager's provider network or otherwise penalized by a pharmacy benefits manager solely because the pharmacy files a complaint, grievance or appeal with any entity.~~ A pharmacy benefits manager shall not neither take action, nor imply or state that it may or will take action, to terminate, suspend, cancel or limit a pharmacy's participation in a pharmacy benefits manager's provider network solely or mainly because the pharmacy files a complaint, ~~grievance or appeal with any entity.~~

e. Any request by a pharmacy for an independent third-party review of a termination or suspension decision shall be considered a complaint and included in the report required by subrule ~~59.7(2)~~ 59.8(2).

ITEM 11. Amend renumbered rule 191—59.7(510B) as follows:

191—59.7(510B) Price change. For purposes of Iowa Code section 510B.7(3), a ~~pharmacy benefits manager may meet the requirements of having to adjust its payment to the pharmacy network provider consistent with a price increase within three business days of the price~~ “price increase notification by a manufacturer or supplier” includes price changes made by national compendia or other services used by a pharmacy benefits manager which take into account, in whole or in part, price changes made by manufacturers or suppliers to help facilitate the development of a drug's maximum reimbursement amount to a pharmacy. A pharmacy benefits manager may comply with the requirements of Iowa Code section 510B.7(3) by keeping a list of current ~~prescription~~ formulary drugs and current maximum reimbursement amounts for those formulary drugs and by updating that list at least every three business days with any ~~price increases~~ maximum reimbursement amount changes. This list shall be made available to pharmacies ~~and pharmacy network providers~~ through a readily accessible and easily usable online format, or in some other readily accessible and easily usable format.

ITEM 12. Amend renumbered subrules 59.8(1) and 59.8(2) as follows:

59.8(1) System to record complaints. Each pharmacy benefits manager shall develop an internal system to record and report complaints. This system shall include but not be limited to the following information regarding each complaint ~~from any pharmacy:~~

a. The reason for the complaint and any factual documentation submitted by the complainant to support the complaint;

b. to f. No change.

- g. The final determination and outcome of the complaint; and
- h. The name of any pharmacy services administrative organization with which the pharmacy has a contract or that is involved in the matter.

59.8(2) *Quarterly complaint summary.* A summary of all complaints received by the pharmacy benefits manager each calendar quarter shall be submitted to the commissioner within 30 days after the calendar quarter has ended. The summary shall include the following:

- a. No change.
- b. A summary of the information listed in paragraph 59.7(4) 59.8(1)“a,” excluding documentation; and
- c. The information listed in paragraphs 59.7(4) 59.8(1)“b,” “d,” “e,” and “g.”

ITEM 13. Adopt the following **new** subrule 59.8(3):

59.8(3) *Inquiries and complaints from the commissioner.*

- a. Pharmacy benefits managers shall comply with Iowa Code section 507B.4A(1) in responding promptly to inquiries from the commissioner, including complaints.
- b. When responding to inquiries and complaints from the commissioner, pharmacy benefits managers shall include the Food and Drug Administration National Drug Code number and the names of the manufacturers of the prescription drugs that are related to the inquiry.

ITEM 14. Amend renumbered rule 191—59.10(507,510,510B) as follows:

191—59.10(507,510,510B) Commissioner examinations of pharmacy benefits managers.

59.10(1) *Cooperation of pharmacy benefits managers with the commissioner.* Pharmacy benefits managers shall cooperate with the commissioner ~~for~~ and comply with the commissioner’s requests to aid with the commissioner’s administration of Iowa Code chapters 507, 507B, 510, and 510B and this chapter, including cooperation and compliance with the commissioner in conducting examinations of pharmacy benefits managers pursuant to Iowa Code chapter 507, and cooperation with the commissioner in conducting investigations pursuant to Iowa Code chapter 507B.

59.10(2) *Maintenance of records.* Pharmacy benefits managers shall maintain for five years the records necessary to demonstrate to the commissioner compliance with this chapter. Pharmacy benefits managers shall provide the commissioner easy accessibility to records for examination, audit and inspection to verify compliance with this chapter.

ITEM 15. Adopt the following **new** subrules 59.10(3), 59.10(4) and 59.10(5):

59.10(3) *Disclosure of payments received by the pharmacy benefits manager.*

a. The commissioner may request, and a pharmacy benefits manager shall disclose to the commissioner, the amount of all payments received by the pharmacy benefits manager, and the nature, type, and amounts of all other revenues that the pharmacy benefits manager receives.

b. For purposes of this subrule, “payments received by the pharmacy benefits manager” means the aggregate amount of the following types of payments:

- (1) A remuneration collected by the pharmacy benefits manager which is allocated to a covered entity;
- (2) An administrative fee collected from the manufacturer in consideration of an administrative service provided by the pharmacy benefits manager to the manufacturer;
- (3) A pharmacy network fee; and
- (4) Any other fee or amount collected by the pharmacy benefits manager from a manufacturer or labeler for a drug switch program, a formulary management program, a mail service pharmacy, educational support, data sales related to a covered individual, or any other administrative function.

59.10(4) *Disclosure of pricing methodology for maximum reimbursement amount.*

a. The commissioner may require, and a pharmacy benefits manager shall submit to the commissioner, pursuant to Iowa Code section 510B.8, information related to the pharmacy benefits manager’s pricing methodology for maximum reimbursement amounts.

b. “Disclosure,” as used in Iowa Code section 510B.8(2), means the disclosure to the commissioner of the information the commissioner requires the pharmacy benefits manager to submit pursuant to Iowa Code section 510B.8(1).

c. Iowa Code section 510B.8(2) “a” permits pharmacy benefits managers to establish maximum reimbursement amounts, as defined in Iowa Code section 510B.1(6), for all multiple-source prescription drugs prescribed after the expiration of any generic exclusivity period. The pricing methodology for determining the maximum reimbursement amounts for multiple-source prescription drugs including but not limited to those prescribed after the expiration of any generic exclusivity period shall be disclosed to the commissioner, if the commissioner requires pursuant to Iowa Code sections 510B.8(1) and 510B.8(2).

d. Iowa Code section 510B.8(2) “b” permits pharmacy benefits managers to establish maximum reimbursement amounts, as defined in Iowa Code section 510B.1(6), for prescription drugs including, but not limited to, those with at least two or more A-rated therapeutically equivalent, multiple-source prescription drugs with a significant cost difference. The pricing methodology for determining the maximum reimbursement amounts for prescription drugs, including but not limited to those with at least two or more A-rated therapeutically equivalent, multiple-source prescription drugs with a significant cost difference, shall be disclosed to the commissioner, if the commissioner requires pursuant to Iowa Code sections 510B.8(1) and 510B.8(2).

e. A pharmacy benefits manager using data sources for determining maximum reimbursement amounts must comply with this paragraph.

(1) The maximum reimbursement amounts that pharmacy benefits managers shall disclose to the commissioner, if the commissioner requires pursuant to Iowa Code sections 510B.8(1) and 510B.8(2), shall be determined, pursuant to Iowa Code section 510B.8(2) “a” and “b,” by using comparable prescription drug prices that are:

1. Obtained from multiple nationally recognized comprehensive data sources including, for example, wholesalers, prescription drug vendors, and pharmaceutical manufacturers for prescription drugs;
2. Nationally available prescription drug prices; and
3. Prescription drug prices that are available to multiple pharmacies in the state of Iowa for purchase locally.

(2) The sources listed in this paragraph and in Iowa Code section 510B.8(2) “c” as sources included among nationally recognized comprehensive data sources are examples of data sources that may be used by pharmacy benefits managers but are not the exclusive data sources that may be used and, if used, that must be disclosed when required by the commissioner.

(3) If a pharmacy benefits manager desires to use a data source not listed in this paragraph and in Iowa Code section 510B.8(2) “c,” the pharmacy benefits manager shall disclose the data source to the commissioner 90 days prior to using the data source.

59.10(5) Confidentiality. Information provided by a pharmacy benefits manager to the commissioner under this rule shall be deemed confidential under Iowa Code section 507.14.

ITEM 16. Amend **191—Chapter 59**, implementation sentence, as follows:

These rules are intended to implement Iowa Code chapters 17A, 505, 507, 507B, 510, 510B and 514L.